

REMARKS

Claims 5-11 have been canceled. New claims 13-17 have been added. Claim 13, which is directed to a solid or semi-solid pharmaceutical composition, now states that the matrix phase contains an active ingredient as disclosed on page 3, lines 16-17 of the specification. Claim 13 also adds hydroxy alkyl cellulose and cellulose esters to the list of components forming the matrix (page 3, lines 36-37 of the specification).

Claim 14 is the same as canceled claim 9. Claim 15 is the same as canceled claim 10.

The examiner rejected claims 5-11 as being anticipated by Klimesch et al. The rejection is made because, according to the examiner, melt extrusion is disclosed (column 2 lines 45-47), PVP is specified (column 2 line 51), flavorings are disclosed (column 4, line 9), theophyllines are specified (column 4 line 39), and as to the claimed particulate the anticipatory composition must possess such because theophylline melts at 270-274°C whereas Klimesch disclose extrusion temperatures of 50-180°C (column 2 lines 64-65).

Lack of novelty can only be established by a single prior art reference which discloses each and every element of the claimed invention. *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984).

Above claim 13 specifies that the matrix contains an active ingredient in the form of a solid solution. Klimesch et al. does not teach this element. Therefore, there should now be no anticipation of the claims.

Claims 5-10 are rejected under 35 USC § 112, first paragraph, because the

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specification, while being enabling for a drug in the second phase or in both phases, does not reasonably provide enablement for a drug only in the matrix. In view of the new set of claims which specify that the matrix contains an active ingredient in the form of a solid solution, applicants believe this rejection no longer should stand.

Claims 5-11 were rejected under obviousness type double patenting as being unpatentable over claims 3 and 13 of US 6,001,391. Applicants submit a terminal disclaimer on separate paper to overcome this rejection.

**Attached is a check in the amount of \$110.00 to cover the one month extension fee.**

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

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